**EXHIBIT 2**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA** MAR 10 2010

Kenneth J. Berk
80 Oakland Street
PO Box 780
Watertown, MA 02472 USA

Telephone: 617-926-6666
Fax: 617-926-6262
ken@pulpdent.com

**DEVICE:**
**Trade Name:** *Pulpdent Fluoride Varnish*
**Classification Name:** Cavity Varnish
**Class:** II
**FDA Product Code:** 76 LBH, 21 CFR Part 872.3260

**PREDICATE DEVICES:**

Scientific Pharmaceuticals *Sci-Pharm Desensitizing Varnish*

Scientific Pharmaceuticals *Sci-Pharm DFV Varnish*

Ultradent *Flor-Opal Varnish White*

3M *Vanish 5% NaF White Varnish*

Colgate *Duraphat*

**DESCRIPTION AND INTENDED USE:**

*Pulpdent Fluoride Varnish* is a resin-based 5% sodium fluoride varnish, formulated without volatile solvents, that is applied to enamel or dentin and is used for professional treatment of dental hypersensitivity by occluding dentinal tubules and by promoting an environment conducive to remineralization.

**COMPARISON WITH PREDICATE PRODUCTS:**

*Pulpdent Fluoride Varnish* is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3260.

**SAFETY AND EFFECTIVENESS:**

*Pulpdent* *Pulpdent Fluoride Varnish* is substantially equivalent in design, composition, performance, intended use, safety and effectiveness to the predicate products listed above that have been on the market and used successfully by dental professionals for more than 15 years with no serious safety or effectiveness problems. *Pulpdent Fluoride Varnish* is formulated without solvents and from materials that have been used in the dental industry for many years without incident.

**REFERENCES: Safety and Effectiveness of Fluoride Varnish**

1. Arnbjerg D. Use of professionally administered fluoride among Danish children. Acta Odontol Scand 1992;50:289-93.

2. Beltrán-Aguilar ED. Fluoride varnishes. A review of their clinical use, cariostatic mechanism, efficacy and safety. Am Dent Assoc. 2000;131(5):589-96.

3. Clark DC. A review of fluoride varnishes: an alternative topical fluoride treatment. Community Dent Oral Epidemiol 1982;10:117-23.

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5. Flanigan PJ, et al. Coating thickness influences fluoride release from white fluoride varnish. 2008 IADR abstract.

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7. Hoang-Dao BT, et al. Clinical efficiency of a natural resin fluoride varnish (Shellac F) in reducing dentin hypersensitivity. J Oral Rehabil 2009;36(2):124-31.

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9. Koch G, et al. Kinetics of fluorine in deciduous enamel after application of fluoride containing varnish (Duraphat). I. Update, distribution and release. Swed Dent J 1982;6:39-44.

10. Olusile AO, et al. Short-term clinical evaluation of four desensitizing agents. J Contemp Dent Pract 2008;9(1):22-9.

11. Ozen T, et al. Dentin hypersensitivity: a randomized clinical comparison of three different agents in a short-term treatment period. Oper Dent 2009;34(4):392-8.

12. Ritter AV, et al. Treating cervical dentin hypersensitivity with fluoride varnish: a randomized clinical study. J Am Dent Assoc 2006;137(7):1013-20.

13. Seppä L. Effects of sodium fluoride solution and a varnish with different fluoride concentrations on enamel remineralization in vitro. Scand J Dent Res 1988;96:304-9.

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15. Stamm JW. Fluoride uptake from topical sodium fluoride varnish measured by an in vivo enamel biopsy. J Can Dent Assoc 1974;40:501-2.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 1 0 2010

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street P.O. Box 780
Watertown, Massachusetts 02471-0780

Re: K093620
Trade/Device Name: Pulpdent Fluoride Varnish
Regulation Number: 21CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: February 23, 2010
Received: February 24, 2010

Dear Mr. Berk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number** (if known): K093620

**Device Name**: *Pulpdent Fluoride Varnish*

**Indications For Use**:

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Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBetz DDS for Dr K. P. Mudry

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



510(k) Number: K093620